MAY 1 7 2001

K003486

510(k) Summary

Device Name:

Trade Name: Stereotaxtic instrument

Proprietary Name: Stereotactic Frame Based System

Common Name: 1. Open Stereotactic System (OSS)

2. Multi-Electrode Advancing System for ZD Device (MEAS)

3. Image Optimized Fixing Pin-
Leibinger® Fixing Pins/Opti Pin

Classification Names: Stereotaxic Instrument
Neurosurgical head holder (skull clamp)
Nonpowered Neurosurgical Instrument

Classification: 84HAW Class II
84HBL Class II
84HAO Class I (exempt)

Reference: 21 CFR 882.4560
21 CFR 882.4460
21 CFR 882.4535

Device Sponsor:

Manufacturer:

Stryker Corporation
Stryker Leibinger GmbH and Co. KG
Bötzinger Straβe 41
D-79111 Freiburg Germany
Registration No.: 8010177

K003486

Distributor: Stryker Corporation
Stryker Instruments
Stryker Leibinger Division
4100 E. Milham Avenue
Kalamazoo, MI 49001
Registration No.: 1811755

Regulatory Class: Class II

Date Prepared: October 31, 2000

Summary of Safety and Effectiveness:

The Stereotactic Frame Based systems and accessories are comprised of three Neurosurgical device:

- The intended use for the Open Stereotactic Ring System (OSS) is designed for head stabilization and imaging in CT and MRI scanners (available with CT-adapter for various CT units).
- The ZD Multi-Electrode Advancing System (ZD MEAS) is an accessory to the Zamorano-Dujovny (ZD) and aiming bow for the frame based stereotaxy to provide submillimetric movement to precisely advance electrodes and cannulas to record electrical signals of brain cells.
- Leibinger® Fixing Pins serve for invasive patient fixation when using the frame based stereotaxy.

The system consists of various implants, instrumentation, and storage containers.

The substantial equivlance of this device is based on the equivalence in intended use, materials, design, and operational principles to the currently marketed predicate devices such as the Stryker Leibinger® STP Complete Module Set/ZD Zamoano-Dujovny Stereotactic Treatment System, Elekta Instruments, AB/Leksell Stereotactic System and Radionics®, Cosman robert Wells Functional Probe.

By: Robin L. Rowe

Robin L. Rowe
Regulatory Affairs Associate

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2001

Ms. Robin L. Rowe
Regulatory Affairs Representative
Stryker Instruments
Stryker Leibinger Division
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K003486
Trade/Device Name: Stereotactic Frame Based System
Regulation Number: 882.4560
Regulatory Class: II
Product Code: HAW
Dated: February 28, 2001
Received: March 1, 2001

Dear Ms. Rowe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K003486

Device Name: **Stereotactic Frame Based System**

Indications For Use: The Stereotactic Frame Based systems and accessories are comprised of three Neurosurgical device:

- The intended use for the Open Stereotactic Ring System (OSS) is designed for head stabilization and imaging in CT and MRI scanners (available with CT-adapter for various CT units).
- The ZD Multi-Electrode Advancing System (ZD MEAS) is an accessory to the Zamorano-Dujovny (ZD) and aiming bow for the frame based stereotaxy to provide submillimetric movement to precisely advance electrodes and cannulas to record electrical signals of brain cells.
- Leibinger® Fixing Pins serve for invasive patient fixation when using the frame based stereotaxy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The- Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003486